APR 2 8 2011

510(k) Summary

Submitter information
Contact person: Garo Mimaryan, Regulatory Technical Specialist

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511 Benedict Avenue
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Date summary prepared: December 17, 2010

Device Trade or Proprietary Name:
IMMULITE®/IMMULITE® 1000 Progesterone Calibration Verification Material (CVM)

Device Common/Usual Name or Classification Name:
Single (Specified) Analyte Controls (Assayed And Unassayed)

Classification Number/Class: JJX / Class I

Classification Panel: Clinical Chemistry (75)

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K103683

Predicate Devices:

Device Name	ADVIA Centaur® Enhanced Estradiol (eE2) Master Curve Material (MCM)
Common name	ADVIA Centaur® Enhanced Estradiol (eE2) Master Curve Material (MCM)
510(k) Number	K102904
Manufacturer	Siemens Healthcare Diagnostics

Device Description:
IMMULITE/IMMULITE 1000 Progesterone assay is traceable to an internal standard manufactured using qualified materials and measurement procedures. Calibration Verification Material (CVM) is traceable to this standard. One set of four vials, 2 mL each, containing low, intermediate and high levels of progesterone in processed human serum, with preservative, and a progesterone-free sample. The Calibration Verifiers are supplied in liquid form, ready to use. Store unopened materials refrigerated at 2–8°C until expiration date. Stable at 2–8°C for 30 days after opening.

Warnings and Precautions:
For in vitro diagnostic use.
Follow universal precautions, and handle all components as if capable of transmitting infectious agents. Source materials derived from human blood were tested and found nonreactive for syphilis; for antibodies to HIV 1 and 2; for hepatitis B surface antigen; and for antibodies to hepatitis C.
Sodium azide, at concentrations less than 0.1 g/dL, has been added as a preservative. On disposal, flush with large volumes of water to prevent the buildup of potentially explosive metal azides in lead and copper plumbing.

Statement of Intended Use:
For in vitro diagnostic use, for the calibration verification of the IMMULITE/IMMULITE 1000 Progesterone assay (LKPW).

Performance:
The traceability, value assignment, and stability of the IMMULITE/IMMULITE 1000 Progesterone calibration Verification Material (CVM) has been validated following procedures of Siemens Healthcare Diagnostics. These Progesterone CVMs are substantially equivalent to currently marketed devices with similar intended uses.

Comparison to the Predicate Device:
Similarities and Differences between the devices and the predicate are shown below:

Similarities

	Device	Predicate
Item	IMMULITE/IMMULITE 1000 Progesterone CVM	ADVIA Centaur eE2 Master Curve Material
Intended Use	For in vitro diagnostic use, for the calibration verification of the IMMULITE/IMMULITE 1000 Progesterone assay (LKPW).	The ADVIA Centaur Enhanced Estradiol Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur® Enhanced Estradiol (eE2) assay.
Matrix	Human Serum	Same
Storage	2°C to 8°C	Same
Stability	Unopened – until expiration date on the vial label	Same

Differences

	Device	Predicate
Item	IMMULITE/IMMULITE 1000 Progesterone CVM	ADVIA Centaur eE2 Master Curve Material
Form	Liquid	Lyophilized
Analytes	Progesterone	Estradiol
Stability	Opened - 30 days	Opened - 14 days

Conclusions:
The IMMULITE/IMMULITE 1000 Calibration verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed ADVIA Centaur eE2 Master Curve Material in intended use and matrix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics
c/o Ernest Joseph
511 Benedict Avenue
Tarrytown, NY 10591 USA

APR 28 2011

Re: k103683
Trade Name: IMMULITE®/IMMULITE 1000 Progesterone Calibration Verification Material (CVM)
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJX
Dated: April 15, 2011
Received: April 18, 2011

Dear Mr. Joseph:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

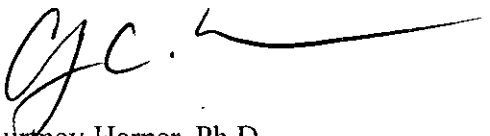
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K103683

Device Name: the IMMULITE®/IMMULITE 1000 Progesterone Calibration verification Material.

Indication for Use:
For in vitro diagnostic use, for the calibration verification of the IMMULITE®/IMMULITE 1000 Progesterone assay (LKPW).

Prescription Use X And/Or Over the Counter Use

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety